

EXHIBIT C

STATE OF NEW MEXICO
COUNTY OF BERNALILLO
SECOND JUDICIAL DISTRICT

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November 20, 2015

Russell F. Dunn, Ph.D., P.E.

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1 RUSSELL F. DUNN, PH.D., P.E.

2 was called as a witness, and after having been
3 first duly sworn, testified as follows:

4

5 EXAMINATION BY MR. DAVIS:

6 **Q.** Good morning, Dr. Dunn. Again, I'm
7 Paul Davis, and, as you know, we just met, I
8 think -- is that correct? -- for the first time?

9 **A.** That's correct.

10 **Q.** Okay. I'm going to bypass some of the
11 usual introductions, because I know you've been
12 deposed several times -- a number times by this
13 time; is that correct?

14 **A.** That is correct.

15 (Whereupon Exhibit 1 was marked as an
16 exhibit.)

17 BY MR. DAVIS:

18 **Q.** Okay. Let me just start by handing you
19 what's been marked as Exhibit 1, the notice for
20 your deposition.

21 And we requested production of
22 documents.

23 Did you bring any documents with you
24 today?

25 **A.** I did. I brought four notebooks of

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1 Because products are used in different
2 applications. You would have to test it in a
3 similar circumstance to that application.

4 **Q.** Well, just make sure this is clear.

5 Do you know of any written standard
6 adopted by the medical device industry for testing
7 a medical device for oxidative degradation effects?

8 **A.** Well, you keep saying a "standard," and
9 I would say that no such thing would exist. And
10 that doesn't preclude a company from being
11 responsible for testing for that effect.

12 **Q.** Okay. I notice in your report you talk
13 about Ethicon's quality systems.

14 Do you recall that?

15 **A.** Yes, I do.

16 **Q.** And are there any written standards for
17 quality systems for medical device manufacturers?

18 **A.** I understand that you want to use the
19 term "standard."

20 There are guidelines and there are
21 principles that are taught for quality systems.
22 There are standards that have to do with risk
23 analysis that would apply to medical devices, and
24 that would affect some of the quality systems.

25 **Q.** Well --

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1 **A.** What you are referring to would be
2 something very specific that can't be applied
3 across many different companies that are all
4 operating in different ways.

5 But there are things outside of
6 standards. There are engineering principles and
7 there are guidelines provided. You just keep using
8 the word "standards." And standards are not
9 written for the quality systems, as -- as you've
10 talked about, other than the ISO 14971 that has
11 implications on quality.

12 **Q.** Okay. We'll get back to ISO 14971.

13 **A.** Uh-huh.

14 **Q.** I do have some questions about that.

15 But, aside from that written standard,
16 do you know of any other written standards specific
17 to the medical device manufacturing industry for
18 quality systems, just specific to that industry?

19 **A.** I don't know that I've looked at --
20 specifically for a standard for quality systems for
21 medical devices.

22 **Q.** So, when you express your opinions in
23 this case regarding Ethicon's quality systems,
24 what -- it sounds like you're just relying on some
25 general principles that you go by in your

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1 profession?

2 MR. BOWMAN: Object to form.

3 BY MR. DAVIS:

4 Q. Let me -- let me strike that and ask it
5 over.

6 Just please explain to me the standards
7 or the guidelines that you applied in this case,
8 the principles that you applied in this case in
9 developing an opinion that Ethicon's quality
10 systems were less than satisfactory.

11 A. Okay. The -- the -- the implication
12 you've made is that, when we're designing or when
13 you have quality systems, that all goes back to
14 standards.

15 I teach all of the chemical engineering
16 seniors at Vanderbilt University, and I teach a
17 course called "Product and Process Design." It is
18 not a course on standards. We have a full textbook
19 of guidelines and principles. It is not built on
20 standards. It's built on engineering fundamentals
21 and principles that we follow in designing products
22 and having quality systems.

23 And even courses that you take on
24 quality and quality engineering are not based on
25 standards. We teach engineering principles. And

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1 to suggest that, if it's not in a standard, it's --
2 it's not scientific or it's not based on scientific
3 principles, does not represent what standards are
4 intended for.

5 Q. Okay. Have you ever heard of 21 CFR
6 Part 820?

7 A. I don't know.

8 Q. Okay. I mean, you don't know what it
9 is, do you?

10 A. Not from memory.

11 Q. Okay.

12 A. I know it's Code of Federal
13 Regulations, and 21 represents the department that
14 it would be associated with. I can't recall -- 19
15 is OSHA. I can't recall which particular division
16 that is of the Code of Federal Regulations. I
17 don't have that one memorized --

18 Q. Well --

19 A. -- whether I've seen it or not.

20 Q. I'm sorry. I apologize. I interrupted
21 you.

22 Were you through?

23 A. Yes.

24 Q. Okay. Well, with respect to the Code
25 of Federal Regulations, you mentioned OSHA.

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1 can't tell you a specific CFR that I've looked at
2 for FDA.

3 **Q.** Have you ever -- I apologize.

4 **A.** Go ahead.

5 **Q.** Have you ever had occasion to review
6 any Food and Drug Administration regulations with
7 respect to any of your work in meshes? You know,
8 pelvic meshes or stress urinary incontinence
9 meshes?

10 **A.** I don't recall at this time.

11 **Q.** Have you ever heard of the Medical
12 Device Directive 93/42/EEC?

13 **A.** I'm not aware of that.

14 **Q.** Okay. Have you ever heard of
15 ISO 13485?

16 **A.** Well, if these are specifically related
17 to medical devices, you're asking the wrong person.
18 I mean, Dr. Guelcher is the medical device expert
19 that I work with.

20 **Q.** Okay.

21 **A.** But I'm not familiar with that.

22 **Q.** What --

23 **A.** He would be the one to ask.

24 **Q.** Okay. Have you ever heard of
25 ISO 10993?

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1 **A.** Yes.

2 **Q.** What is ISO 10993?

3 **A.** I don't -- I don't know off the top of
4 my head. I know that I've heard of that -- I think
5 I've seen that even referenced in the documents
6 from Ethicon.

7 **Q.** Have you ever had occasion to use
8 ISO 10993?

9 **A.** Not that I'm aware of.

10 **Q.** Have you ever had the occasion to
11 review ISO 10993?

12 **A.** I believe I have, but unless I see the
13 document, I don't have numbers memorized.

14 **Q.** Okay.

15 **A.** If you want to provide the standard to
16 me, I'd be happy to look at it.

17 **Q.** Okay.

18 **A.** But I can't answer the question based
19 on a number alone.

20 **Q.** Okay. Have you ever heard of the
21 General Program Memorandum G-95-1?

22 **A.** Okay. If -- if you're going to keep
23 giving numbers, I would ask that you please provide
24 that document to me so I can see if I've seen it
25 before.

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1 Q. And I --

2 A. You're asking me if I recall a number.

3 Q. Okay.

4 A. Not as I sit here right now. But, if I
5 saw the document, I might recall if I've seen it.

6 Q. Well, let me ask you this way: Have
7 you ever read any Food and Drug Administration, you
8 know, documents that discuss the subject of medical
9 devices and -- and what kind of, you know, testing
10 needs to be done on them?

11 A. Again, you're -- you're specifically in
12 Dr. Guelcher's area for medical devices and
13 biocompatibility of medical devices.

14 Q. With respect to a medical device, can
15 you define the concept of harm?

16 MR. BOWMAN: Object to form.

17 BY MR. DAVIS:

18 Q. Well, let me state it this way: With
19 respect to a medical device, can you define the
20 term "harm"?

21 MR. BOWMAN: Same objection.

22 THE WITNESS: "Harm" is a term that is
23 used in the failure mode and effects analysis. It
24 is generally related to the severity ranking that
25 you have in a failure mode and effects analysis.

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1 I -- I teach failure mode and effects
2 analysis as part of the instruction at Vanderbilt
3 University. When you define severity, every
4 company defines it -- you're giving guidelines for
5 what harm or severity rankings could even
6 represent, in terms of -- is it death? Is it an
7 injury that requires more surgery? Companies have
8 to define that for the product that they're looking
9 at. They have to provide a legend.

10 There is nothing like what you have
11 described. There's no -- there are guidelines that
12 are given that you can look at for how you can
13 define harm and how you can rank harm, but every
14 company has to come up with that and provide that
15 themselves as they're going through the failure
16 mode and effects analysis and as they're looking at
17 the potential effect of -- of failure modes.

18 BY MR. DAVIS:

19 Q. It sounds like I'm hearing you say that
20 there is no specific definition for the term
21 "harm."

22 A. "Harm" is a category, and the company
23 has to define the -- the different levels of harm.
24 We call that severity. You -- companies actually
25 define that.

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1 In fact, they give a severity ranking
2 of 1 to 10, and, next to each number, they define
3 what that means in terms of harm. Like a 1 would
4 be no effect, no harm. A 10 would be death, severe
5 harm.

6 Do you -- you understand what I'm
7 saying? That's how it's defined.

8 **Q.** Okay. Can you define the term "hazard"
9 with respect to a failure modes and effects
10 analysis for a medical device?

11 MR. BOWMAN: Object to form.

12 THE WITNESS: Let me -- (reviews
13 documents.) I would refer you -- I understand that
14 you -- you want a quick general statement to a very
15 complex question.

16 I will refer you to ISO 14971, 2007
17 version. If you go to Annex D, and you find in
18 Section D(2), "Hazards and Hazardous Situations."

19 The reason I can't give you a one-line
20 definition of "hazards," you'll see that there are
21 two pages that talk about a variety of different
22 hazardous situations that occur with medical
23 devices, that is specific to medical devices.

24 So a hazardous situation, as they've
25 defined it, is something that could cause or lead

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1 to harm.

2 If we want to find out what "harm" is,
3 again, we can look at that standard and get some
4 guidance on the effect that it has on a patient.
5 And guidelines are given, but there's -- it's a lot
6 more involved than the simple one-line definition.

7 BY MR. DAVIS:

8 Q. I noticed you just referenced ISO 14971
9 again.

10 When was the first time that you ever
11 heard of that ISO?

12 MR. BOWMAN: Object to form.

13 THE WITNESS: I have no idea.
14 Apparently, I purchased it -- a copy of it online
15 January 16th of 2014.

16 BY MR. DAVIS:

17 Q. Okay.

18 A. That's the copy that I have printed
19 out. I had other documents that referenced it, but
20 I didn't have the actual standard, I believe -- I
21 may have received a copy of it prior to that, but I
22 actually purchased my own copy online on that date.

23 Q. Let's see. Your -- what exhibit number
24 did we make your report in the TVTO case? I think
25 you have it over there.

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1 Exhibit 6; is that correct?

2 MR. BOWMAN: Object to form.

3 THE WITNESS: I didn't use the number
4 ISO 14971. But I'm telling you, what I referenced
5 was guidelines for failure mode and effects
6 analysis, and if you want to go and get the book,
7 you'll see it is based on ISO 14971.

8 BY MR. DAVIS:

9 Q. I've got the book.

10 A. Okay.

11 Q. I'm going to get to it.

12 A. Okay.

13 Q. But right now I just want to know, is
14 it fair to say that you were not familiar with
15 ISO 14971 at the time you wrote the report that's
16 Exhibit 6?

17 A. That's not fair to say. I told you
18 that that was referenced in this book.

19 Q. Okay. When was the first time -- let
20 me ask you this: When was the first time you read
21 ISO 14971?

22 A. The actual ISO was probably January of
23 2014.

24 Q. Okay. Have you ever had the occasion
25 to perform a risk assessment pursuant to ISO 14971?

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1 **A.** The risk assessment for ISO 14971 is
2 specifically telling you how to perform risk
3 analysis and failure mode and effects analysis for
4 medical devices.

5 I have only performed failure mode and
6 effects analysis hundreds of times for nonmedical
7 devices. I teach those and require students to do
8 failure mode and effects analysis. The technique
9 is the same whether it's a medical device or not.

10 So you keep bringing it back to
11 ISO 14971 and saying have I applied it specifically
12 to a medical device. The answer is no.

13 Have I applied failure mode and effects
14 analysis? Hundreds of times.

15 **Q.** Okay. Well, you say the standard's the
16 same whether it's a medical device on not. So let
17 me follow up on that.

18 **A.** No, I didn't say the standard was the
19 same. I said failure mode and effects analysis,
20 the technique is the same.

21 **Q.** I'll use your term. So the technique
22 is the same. So let me follow up on that.

23 **A.** Yes.

24 **Q.** If you've got an existing device for
25 which you've done a failure modes and effects

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1 the body?

2 A. I agree that I am qualified to tell you
3 the effects of oxidative degradation on the polymer
4 itself and how it changes the polymer properties.
5 And I agree that Dr. Guelcher is the expert that I
6 work with who can tell you the effect on the body.

7 Q. Well, I appreciate that. But I just
8 have a very simple question. If you'll just answer
9 it, I'll move on.

10 Will you agree that you personally are
11 not qualified to evaluate the effects or potential
12 effects of oxidative degradation of Prolene on the
13 body, the human body?

14 A. I -- I will reiterate that I can -- I
15 am qualified to talk about the changes in the
16 polymer properties --

17 Q. That's not my question. I'm sorry to
18 interrupt you, but. . .

19 A. I would defer that to Dr. Guelcher.

20 Q. So the answer to my question? Yes?

21 A. No, the answer to your question is to
22 an extent.

23 Q. Well -- okay.

24 A. I know you think it's a simple
25 question, but, if I don't think it's a simple

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1 understand, for instance, did you try to then go
2 find or ask for all these documents, or not?

3 A. Not that I recall, because these were
4 referenced in the FMEA, and what I was interested
5 in was what was not included in the FMEA.

6 Q. Okay. Do you have any experience in
7 developing quality systems for medical devices?

8 A. Well, the FMEAs -- that's a hard
9 question for me to answer. I haven't -- I teach
10 FMEAs, and I teach it to students who end up
11 working in all kinds of areas. So -- I haven't
12 applied it in a specific company, but I teach these
13 concepts to students that go out and work for
14 medical companies and. . .

15 Q. Have you ever taught about how to
16 develop quality systems specifically for medical
17 devices?

18 A. I teach generically how to do product
19 and process design, and it's applied by chemical
20 engineers to numerous industries. I don't teach
21 about a specific industry.

22 Q. What -- what does "design controls"
23 mean? I mean specifically for medical devices.

24 A. It would be parameters that you
25 establish that you want to control those

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1 characteristics.

2 Q. Okay. What -- what are the design
3 controls generally accepted for medical devices?

4 A. It would be different for different
5 medical devices.

6 Q. Can you -- can you just tell me what
7 some of the design controls are for medical
8 devices?

9 A. Oh. Well -- so, if I talked about the
10 mesh component, because that's the component that
11 I'm looking at for the medical device for the
12 Prosima, certain design controls would be things
13 like the weave, the diameter of the fiber, the
14 density.

15 Q. That --

16 A. You're shaking your head no.

17 Q. Maybe we're on a different wavelength,
18 because I'm asking you -- the process, the process
19 of design controls, in designing and developing a
20 medical device. Can you tell me what the design
21 control processes are?

22 A. You're going to have to ask a -- I
23 don't know what you're asking exactly.

24 Q. That's fair enough.

25 Do you have any experience in

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1 maintaining a quality system for medical devices in
2 particular?

3 A. It's no different for medical devices
4 than other devices.

5 Q. So is the answer you don't have any
6 specific experience for medical devices, or you do?
7 Either you do or you don't.

8 A. I've never manufactured medical
9 devices.

10 Q. So you've never had any experience in
11 maintaining a quality system for medical devices;
12 is that correct?

13 A. But I maintain that the quality systems
14 I've been involved in in my work career are the
15 same as those types of systems you'd put in place
16 for medical devices.

17 Q. With that explanation, is the answer
18 yes?

19 A. Ask the question again now.

20 Q. Have you ever had any experience in
21 maintaining a quality system for a medical device
22 in particular?

23 A. Not specifically for a medical device,
24 but quality systems that I've maintained and been
25 involved in in manufacturing operations are -- are

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1 the same or very similar.

2 Q. Have you ever had any experience in
3 auditing quality systems for medical devices?

4 A. Not specifically medical devices. Only
5 other polymer-based products.

6 Q. And can you give me an overview of how
7 you performed your audits?

8 A. Of other polymer products?

9 Q. Yes.

10 A. Sure. You -- you asked a question
11 before that I guess I misinterpreted about design
12 controls. So -- in auditing polymer-based products
13 that I've been involved in and that we would
14 manufacture, we had certain specifications or
15 criteria, what I would call design controls.
16 Certain parameters that you could measure that you
17 were trying to target in the manufacturing process.

18 In -- in trying it maintain a quality
19 system, you would go and pull random samples and
20 test those versus your design controls.

21 Q. Okay.

22 A. If I'm understanding the question
23 correctly.

24 Q. Now, do you have any experience in
25 preparing any design controls for medical devices?

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1 For the design and development of medical devices,
2 that is.

3 A. Not specifically for medical devices;
4 only for other polymer-based products.

5 Q. Okay. And what were those design
6 controls?

7 A. For other polymer-based products?

8 Q. Yes.

9 A. They varied, depending on what the
10 product was.

11 Q. Okay. I know it's your testimony, your
12 opinion, that Ethicon's Prolene is subject to
13 oxidative degradation.

14 I'd like to follow up on that and ask
15 you, are there any degradation products of the
16 oxidative degradation of Prolene?

17 A. Not typically. It -- the oxidative --
18 oxygen -- it -- it -- it depends on how it
19 oxidizes. I need to be careful with that, because
20 there's different oxidizing agents that can react
21 with it. And, depending on the oxidizing agent
22 that reacts with it, I think there can be some
23 potential for byproducts.

24 In general, oxygen is attaching from
25 some type of reactive oxygen species or even oxygen

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1 from the air, and it breaks the chain, the long
2 chain length of the polypropylene, into shorter
3 chains.

4 Q. In that case, let's focus on Prolene in
5 the body specifically.

6 A. Okay.

7 Q. Are there -- I know you've given the
8 opinion that, in the body, there is oxidative
9 degradation going on of the Prolene.

10 So I want to know, are there any
11 degradation products resulting from the oxidation
12 that -- degradation that you believe is occurring?

13 MR. BOWMAN: Object to form.

14 THE WITNESS: Can you point to in my
15 report where I say that it's oxidizing in the body?

16 You said I said that it oxidized in the
17 body. That's what -- there are reactive oxygen
18 species in the body, but that specifically -- that
19 oxidative mechanism inside the body is specifically
20 what Dr. Guelcher reports on.

21 BY MR. DAVIS:

22 Q. Okay. You don't have an opinion as to
23 whether Prolene oxidizes in the body --

24 MR. BOWMAN: Object to form.

25

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1 BY MR. DAVIS:

2 Q. -- is that correct?

3 A. No, that's not correct.

4 Q. Okay. Do you -- is it your opinion
5 that Prolene, after implantation in the human body,
6 is undergoing oxidative degradation?

7 MR. BOWMAN: Object to form.

8 THE WITNESS: Yes.

9 BY MR. DAVIS:

10 Q. Okay. And where is that in your
11 report? I thought a minute ago you said -- you
12 said it's not in your report.

13 A. It's not. I don't offer that as an
14 opinion, and I'm not going to testify on that. But
15 you asked if I believed that's happening. And,
16 yes, I do believe that's happening.

17 Q. Okay.

18 A. But, the actual mechanism for how it's
19 happening -- I say that because I've read
20 Dr. Guelcher's report.

21 Q. Okay. But -- so -- my question then --
22 follow-up -- is, will you agree that it's not
23 within your expertise to evaluate whether Ethicon's
24 Prolene is undergoing oxidative degradation after
25 implantation in the body?

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1 **A.** I'm sorry. I was talking about the
2 effect on the -- on the polypropylene itself.

3 **Q.** Well, thank you, because -- let's get
4 back to -- let me just start over with my question,
5 because that was not my question.

6 My question was do you have any
7 expertise on the effects of oxidative degradation
8 of Prolene on tissue in the body?

9 **A.** I do not.

10 **Q.** Thank you. Do you know what Fenton's
11 reagent is?

12 **A.** Not off the top of my head.

13 **Q.** Have you ever heard of Fenton's
14 reagent?

15 **A.** I don't know if I have or not. I mean,
16 I don't recall it.

17 **Q.** Okay. I noticed in your report you --
18 you expressed the opinion that Ethicon's complaint
19 handling was not satisfactory.

20 Do you recall that?

21 **A.** I would have to look back -- if there's
22 a specific location -- yes.

23 **Q.** Look at the -- what? -- fourth-to-last
24 page, the third-to-last paragraph.

25 **A.** Yes.

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1 Not a patient and not a medical doctor.

2 Q. With respect to medical devices, please
3 explain, what is "complaint handling"?

4 MR. BOWMAN: Object to form.

5 THE WITNESS: I know what it is
6 relative to -- to polymer failure issues. And
7 complaint handling -- because that's the background
8 that I have. And complaint handling is getting
9 materials back where there's been some kind of
10 issue with -- with that particular product and
11 running scientific tests on it to see if you can
12 determine if there's a problem with it.

13 BY MR. DAVIS:

14 Q. Are there any written standards for --
15 for complaint handling with respect to medical
16 devices?

17 A. I don't know that there are standards.

18 Q. Okay. Well -- but you say that
19 complaint handling is part of a quality system.

20 Do you see that?

21 A. Yes.

22 Q. Okay. And so what's your basis for
23 saying that complaint handling is part of a quality
24 system?

25 A. My basis is working in industry, where

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1 **Q.** Okay. And I notice you used the term
2 "risk management" also.

3 Is that somehow different from risk
4 assessment?

5 **A.** No. They're all related. The only
6 thing I would tell you is risk analysis, in my
7 opinion, gets down to the very specific tools that
8 you employed to look at the potential hazards. So
9 it's a subset of risk -- of risk assessment.

10 And when you combine risk assessment
11 and risk analysis all together, you come up -- the
12 overarching category is your risk management plan.

13 **Q.** Okay. Would you agree that you're not
14 qualified to opine as to whether oxidative
15 degradation of Prolene in the body causes any -- or
16 has the potential to cause any harm to the body?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: I can only testify to the
19 changes in the polymer itself.

20 BY MR. DAVIS:

21 **Q.** Okay. So the answer would be that you
22 do not have the expertise that I just asked about?

23 **A.** No. It would -- it would require
24 somebody with expertise inside the body to talk
25 about how that would ultimately affect.

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1 **Q.** And you have no expertise about matters
2 inside the body, correct?

3 **A.** To know the effect on the tissue -- I
4 agree with what you're saying.

5 **Q.** Okay. Have you ever heard of a
6 biocompatibility risk assessment?

7 **A.** I've -- I've heard of biocompatibility
8 testing. I'm not sure that I've heard it combined
9 specifically with biocompatibility risk assessment.

10 **Q.** Okay. So do you know any -- any
11 standards, written standards that apply to
12 biocompatibility risk assessment?

13 **A.** Only what I've read. I've not been
14 involved in biocompatibility testing.

15 **Q.** Okay. Do you have any expertise in
16 evaluating a biocompatibility risk assessment?

17 **A.** It -- it depends on the parameters that
18 are being evaluated. In some cases, I could have
19 some expertise.

20 **Q.** Well --

21 **A.** More on the chemical side. If it's
22 a -- if there's some chemical testing that's done
23 that I needed to look at and evaluate what that
24 result is saying, I have expertise in that
25 background. But I don't run biocompatibility

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1 it has antioxidants in it.

2 Q. Okay. Please explain to me your
3 scientific basis for saying that Prolene is the
4 most easily oxidizable polymer.

5 A. I'm sorry. If I said it that way, I'm
6 saying polypropylene-based resin is the most easily
7 oxidized polymer. The only thing keeping Prolene
8 from oxidizing as fast as polypropylene without
9 antioxidants is the fact that it has some
10 antioxidants in it.

11 Q. Okay. So let's get back to this
12 question. You said, "Prolene oxidizes readily."
13 Explain what you mean by "readily."

14 A. That as soon as the antioxidants are
15 expended, Prolene will oxidize easily. It's the
16 most easily oxidized polymer, polypropylene.

17 Q. In the body, how long does it take for
18 the antioxidants to be depleted from Prolene?

19 A. It would vary.

20 Q. Well, what's the shortest period of
21 time?

22 MR. BOWMAN: I'm going to object to
23 form.

24 BY MR. DAVIS:

25 Q. Or do you have the expertise to know

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1 what the shortest period of time is?

2 **A.** I haven't studied that.

3 **Q.** Okay. Well, I understand you haven't
4 studied it.

5 Do you have any expertise to evaluate
6 the shortest period of time for Prolene to oxidize
7 within the human body?

8 MR. BOWMAN: Object to the form.

9 BY MR. DAVIS:

10 **Q.** And when I say "oxidize," I mean use up
11 or deplete the antioxidants.

12 **A.** I'm struggling with the "any
13 expertise." If you gave me samples that were in
14 the body for certain periods of times, I have the
15 expertise to analyze them to see if they have
16 oxidized. I don't know if that's what you're
17 asking.

18 **Q.** That's not what I was asking.

19 **A.** Well, you said "any expertise." I do
20 have some expertise. If you gave me the samples, I
21 have the expertise to test them to see if they're
22 oxidized. I thought that's what you asked, "any
23 expertise."

24 **Q.** Now, can you tell me whether literature
25 reviews have any role in the process of assessing

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1 risk of degradation of Prolene in the body?

2 A. Certainly.

3 Q. What is the role of literature reviews
4 on the process of assessing risk of degradation in
5 the body with respect to Prolene?

6 A. It can help you understand whether the
7 scientists have tested at that point.

8 Q. Okay. And that raises this question:
9 In your report, you say that, if Ethicon had
10 considered oxidative degradation, it would have
11 done some further testing.

12 Do you recall that?

13 A. Absolutely.

14 Q. Tell me what that -- what the testing
15 is that you're referring to.

16 A. Okay. Well, clearly, they were looking
17 at explants, ophthalmic, vascular -- they were
18 looking at sutures back in the '80s. And I talk
19 about that in Section 3.2 of the report.

20 Q. I don't want to know what they did in
21 the past.

22 I want to know what testing are you
23 saying they should have done here, twice in your
24 report.

25 A. There's -- there's a lot they could

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1 **A.** I did.

2 **Q.** What animal testing, additional animal
3 testing needed to be done? Explain what they
4 needed to do.

5 MR. BOWMAN: Object to form. This is
6 asked and answered.

7 MR. DAVIS: No, it's not.

8 THE WITNESS: I'm not going to, in two
9 minutes, design a highly technical study. You
10 would do it as a group and get together and talk
11 about -- just like they did in their memos.
12 They're -- they're getting together and talking
13 with multiple parties.

14 You would get the right individuals
15 together and -- and say, we're seeing oxidation at
16 this point; what can we do as the next steps to
17 further verify this is occurring?

18 BY MR. DAVIS:

19 **Q.** Well, you've expressed the opinion
20 twice in your report that Ethicon needed to do
21 further testing.

22 Can you sit here today and tell me any
23 specific test, describe any specific test that
24 you're saying Ethicon should have done?

25 MR. BOWMAN: Objection as asked and

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1 answered.

2 BY MR. DAVIS:

3 Q. Please answer the question.

4 A. I'm telling you that they should have
5 more explants -- they should have implanted in --
6 in more controlled environments and taken those
7 explants and done much more FTIR, much more
8 microscopy. All the things that they were doing
9 that they stopped doing. They should have done
10 crack evaluations. All of that would have led them
11 to understand that this is occurring in the body.

12 Q. Okay. Are you basing this -- these
13 opinions on needing further tests, are you basing
14 them on any written standard?

15 A. It's not a standard that requires you
16 to do this.

17 Q. It's just your opinion?

18 MR. BOWMAN: Object to form.

19 THE WITNESS: It's -- it's my opinion,
20 based on teaching product design and a standard of
21 care that companies have to have. You keep saying
22 a "standard" because -- standards are very
23 specific. I think that they had a duty as a
24 manufacturer to do more testing based on the --
25 their own internal testing.

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1 BY MR. DAVIS:

2 Q. I want to follow up on a subject that I
3 talked about a few minutes ago that I omitted
4 something.

5 Can you give us at least a general time
6 frame, as best you can, about how long it takes
7 Prolene to oxidize in the body?

8 MR. BOWMAN: Object to form.

9 THE WITNESS: I believe I said --

10 BY MR. DAVIS:

11 Q. What I mean by "oxidize" again is
12 deplete its antioxidants.

13 A. I believe what I said was it's
14 variable. As a chemical engineer, it's variable
15 because you need the species to react with it.
16 There's a lot of other parameters, including the
17 stress that the material's under.

18 So, no, I can't give you a time frame
19 because it would vary in different patients.

20 Q. Okay. Can you give me your estimate of
21 the minimum time frame?

22 A. I've not tried to determine that.

23 Q. Okay.

24 A. Well, can I --

25 MR. BOWMAN: Just wait for a question.

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1 MR. DAVIS: I'm sorry?

2 MR. BOWMAN: I said I could clear this
3 up with deposition testimony that was taken, you
4 know, a year ago on the issue.

5 MR. DAVIS: Uh-huh.

6 MR. BOWMAN: Would you -- I mean, I
7 could also just tell you what happened.

8 MR. DAVIS: Okay.

9 MR. BOWMAN: It was a misprint. He
10 didn't look at any of the exemplars for that
11 report --

12 MR. DAVIS: Okay.

13 MR. BOWMAN: -- the TVTO report.

14 MR. DAVIS: Okay.

15 BY MR. DAVIS:

16 Q. And then let me just follow up.

17 Do you rely in this case on any
18 exemplar meshes in forming your opinions?

19 A. No. It's not in my report. No.

20 Q. Okay. Bear with me one second.

21 A. Sure.

22 Q. In your -- let's go back again to
23 Exhibit 6, your earlier TVTO report.

24 A. Got it.

25 Q. And on that same page, the very bottom

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1 of that third page, you have a bullet point where
2 you say, "Ethicon has not studied the effect of
3 polypropylene's reactivity in vivo."

4 Do you see that?

5 **A.** Yes.

6 **Q.** And you took that bullet point out in
7 your current report.

8 So I would like to know, why did you
9 take that out?

10 MR. BOWMAN: Object to form.

11 THE WITNESS: Because both Dr. Guelcher
12 and I have written reports on the Jasso matter, and
13 he covers that in his report.

14 BY MR. DAVIS:

15 **Q.** Okay. What is polypropylene's
16 reactivity in vivo? I mean, are you qualified to
17 discuss that, or is that for Dr. Guelcher to
18 discuss?

19 **A.** Well, I know -- I will let him discuss
20 that. I know it involves the reactive oxygen
21 species in the body, but that's his area of
22 expertise.

23 **Q.** That's not your area of expertise, is
24 it?

25 **A.** No. Just that, if the oxidizing agent

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1 is present and if the polypropylene oxidizes, what
2 the effect will be.

3 Q. In your current report on page -- on
4 the second page, in the third paragraph, you
5 reference the design process used by Ethicon for
6 the Prosima device.

7 Do you see that?

8 A. Where?

9 Q. In the third paragraph at the top of
10 the second page of Exhibit 2, the paragraph begins,
11 "The focus of this report."

12 Do you see which paragraph I'm on?

13 A. Yes.

14 Q. And in that paragraph you reference the
15 design process used by Ethicon for the Prosima
16 device.

17 Do you see that?

18 A. Yes.

19 Q. Can you tell me what standards govern
20 that design process?

21 MR. BOWMAN: Object to form as asked
22 and answered.

23 THE WITNESS: No. Other -- other than
24 I -- I'm really specifically talking about, in the
25 design process, the design FMEA, and we've already

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1 **Q.** So, again -- what I'm trying to get at,
2 though, are you saying that you need to go back to
3 the FMEA itself and now create a new version of it?
4 Is that what you mean by "update"?

5 **A.** Yes. Okay. So what is typically done
6 is you have revisions, and you can have Revision B,
7 C, D.

8 So, whenever you do a revision to an
9 FMEA, what you go -- and you look at the table, the
10 table of the potential failure modes, all the
11 analysis, much of which you have seen already
12 today. And you look at any items that already
13 exist that you need to update information on,
14 you've learned something new about it. Or perhaps
15 there's some new potential failure modes that you
16 don't have a line item for that you need to add.
17 That's updating.

18 **Q.** Okay. I understand this concept that
19 you're expressing about -- about evaluating, you
20 know, new risks and so forth.

21 But are you saying that there's a
22 standard somewhere that required you to actually go
23 back and put it all in a revision to the FMEA?

24 MR. BOWMAN: Object to form.

25 THE WITNESS: Yes. It's a living

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1 document. You -- as you learn more -- any time --
2 a simple example was the internal studies.

3 And, as they felt that oxidation was
4 occurring -- whether they -- whether they think
5 it's really oxidizing or not, there was enough
6 evidence in the '80s and then even later with
7 external consultants coming in and saying Prolene
8 will oxidize, polypropylene will oxidize.

9 All of this should have been fed back
10 into the appropriate failure mode and effects
11 analysis so that that was adequately evaluated and
12 investigated.

13 BY MR. DAVIS:

14 Q. Okay. You've already testified that
15 "risk management" is a much broader term than an
16 FMEA risk analysis, right?

17 A. Right. But the FMEA is the tool they
18 choose -- they chose to use to systematically look
19 at all the risk and to analyze all the risk --

20 Q. Okay.

21 A. -- and all the potential failure modes.

22 So if you're telling me there's a
23 potential failure mode that didn't end up on the
24 FMEA, that's inappropriate. That's inaccurate.
25 Because they chose the FMEA as their tool.

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1 is it?

2 A. No, it shouldn't be. The FMEA is
3 specifically looking at safety.

4 Q. Well, a risk -- a benefit/risk analysis
5 is looking at safety, isn't it?

6 MR. BOWMAN: Object to form.

7 THE WITNESS: Not necessarily.

8 BY MR. DAVIS:

9 Q. Hmm. Okay.

10 A. It can look at safety as part of it.
11 And it certainly can look at the risk associated
12 with something that's unsafe.

13 Q. Okay.

14 A. In many cases a company will choose to
15 do something that's unsafe because the benefit
16 financially is worth it to them.

17 Q. By the way, you talk about page 6 of
18 Exhibit 9.

19 I take it you'll agree that -- that --
20 you agree with the process depicted in the chart on
21 page 6, right?

22 A. I -- I don't have a problem with this
23 exhibit.

24 Q. Okay. Well, I mean, you would agree
25 that 14971 ISO is an authoritative source to you,

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1 right?

2 A. It -- it is a good source. It is
3 updated, too, you know?

4 Q. Okay. And, of course, you can see on
5 page 6 in the chart, it -- when it wants you to
6 feed information back into the FMEA, it actually
7 has arrows directing you to do that, right?

8 A. It -- it is showing that. And I looked
9 at that previously.

10 Q. It doesn't show an arrow putting --
11 directing the postproduction information to go back
12 into the risk analysis, does it?

13 A. It -- it does not. And that would be
14 something that I would suggest that they would
15 change in the next version. Because it says that
16 it goes into the risk management process. And when
17 you look at risk management, it covers the whole
18 line. And I'm telling you, the only place it goes
19 back is to the FMEA.

20 Q. Look at page 39 for a second, please,
21 sir, of Exhibit 9.

22 A. Yes.

23 Q. Do you understand that the -- the
24 standard for medical devices actually gives
25 instructions on what to consider state of the art?

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1 chemically in published literature, such as the
2 fact that polypropylene has been known to oxidize
3 for decades. So I agree.

4 Q. In fact, you -- in your own report,
5 you -- you point out that polypropylene has been
6 extensively studied since the 1960s, right?

7 A. Outside the body, yes.

8 Q. Okay.

9 Now, do you see where, at the bottom of
10 page 3 of 6, the FDA goes on to explain that, in
11 analyzing the need for biocompatibility testing,
12 you should follow ISO 10993? Do you understand
13 that?

14 A. Yes.

15 Q. And do you also --

16 A. Can -- I just want to point out one
17 more time that biocompatibility and -- and chemical
18 degradation were in different categories in the
19 FMEA, and everything associated with
20 biocompatibility that we're talking about was not
21 in the category that I am discussing.

22 So continue on.

23 Q. Because you're saying that oxidative
24 degradation is a chemical process, as opposed to --
25 as opposed to going to biocompatibility?

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1 **A.** That is correct. While the chemical
2 reaction can take place in the body, it is
3 categorized as a hazard -- and I'll find it for
4 you -- in the ISO standard for the FMEA where it's
5 got examples of hazards and degradation is under
6 the chemical hazard, not biocompatibility. They
7 clearly distinguish the differences.

8 So now all we're talking about is
9 biocompatibility, which is not the subject of my
10 report.

11 **Q.** Okay. Then let's -- let's look at
12 ISO 10993 then.

13 MR. BOWMAN: I'm going to have the same
14 warning. He has no opinions related to 10993.

15 MR. DAVIS: That's fine. If he has
16 none --

17 MR. BOWMAN: He's got a report. You
18 can just look at the report. We've gone through
19 almost everything except for one of the opinions in
20 the report. And I think that's what we're going
21 through now. So I'm guessing -- that's why I'm
22 letting this go on, but this is. . .

23 (Whereupon Exhibit 16 was marked as an
24 exhibit.)

25

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1 BY MR. DAVIS:

2 Q. Have you ever -- are you familiar with
3 ISO 10993 now?

4 MR. BOWMAN: Object to form.

5 THE WITNESS: I may have seen it at
6 some point.

7 BY MR. DAVIS:

8 Q. Will you agree that it is the
9 international standard recognized by the FDA for
10 biological evaluation of medical devices?

11 MR. BOWMAN: Object to form. Beyond
12 the scope of his report.

13 THE WITNESS: I don't -- I haven't
14 looked into that. I don't know.

15 (Whereupon Exhibit 17 and Exhibit 18
16 were marked as exhibits.)

17 BY MR. DAVIS:

18 Q. Let me hand you Exhibits 17 and 18.

19 Do you see where Exhibit 17 is -- is a
20 subset of ISO 10993? It's Part 9 that deals with
21 the framework for identification and quantification
22 of potential degradation products?

23 A. Yes.

24 Q. And is it your testimony that -- that
25 this standard doesn't apply -- doesn't concern

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1 chemical degradation or oxidative degradation in
2 particular?

3 MR. BOWMAN: Object to form. Beyond
4 the scope of his report. Not a biological expert.
5 He's a chemical engineer.

6 MR. DAVIS: I agree.

7 MR. BOWMAN: Design expert.

8 THE WITNESS: I don't know. I haven't
9 looked at this.

10 BY MR. DAVIS:

11 Q. Okay. And do you see in Exhibit
12 Number 18 that it deals specifically with -- it's
13 Part 13 of the ISO, and it deals specifically with
14 identification and quantification of degradation
15 products from polymeric medical devices? Do you
16 see that?

17 A. Yes.

18 Q. And do you see that on page 3 -- look
19 at page number 3 of this Exhibit 18. Do you see it
20 specifically deals with oxidative degradation? Do
21 you understand that?

22 MR. BOWMAN: Object to form. Beyond
23 the scope of his report, not referenced in his
24 report.

25 THE WITNESS: I see that.

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1 lots of documents.

2 I don't -- if you have a specific one
3 that you want to point out that shows me that they
4 considered oxidative degradation, not keep talking
5 about this biocompatibility testing, which doesn't
6 show me in any way whatsoever that they tested for
7 oxidation, I'd be happy to look at any document you
8 have.

9 BY MR. DAVIS:

10 **Q.** Okay. Look at the last page of
11 Exhibit 26, please, sir.

12 Do you see the second line number on
13 that page listed a hazard, "Loss of Mechanical
14 Integrity Postoperative."

15 Do you see that?

16 **A.** Yes, sir.

17 **Q.** And do you see what their plan is?
18 "Clinical study design will assess this parameter."
19 And they referenced a clinical literature search.

20 You certainly understand that that's an
21 appropriate means of addressing this potential
22 hazard, don't you?

23 **A.** If -- if the literature is applicable.

24 **Q.** Okay. So if the -- if there's -- if
25 there is applicable literature, you agree that a --

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1 one proper means of evaluating this potential
2 hazard is a clinical literature search, right?

3 A. I don't -- I don't believe in this case
4 that is possible, considering their own internal
5 tests where they see degradation and they're in the
6 best position to evaluate their own product.

7 Q. Sir, you haven't done a clinical
8 literature search on the subject matter that you're
9 talking about, have you?

10 A. I've -- I've looked at a lot of --
11 clinical research is -- is not my specialization.
12 Clinical documents is not my specialization. While
13 I've looked at a lot of clinical publications,
14 that's not -- that's not my area of expertise.

15 Q. Okay. So you agree, then, that it
16 would be -- it's not your area of expertise to
17 evaluate whether or not Ethicon's clinical
18 literature search on this subject of loss of
19 mechanical integrity postoperative is adequate?

20 A. It is within my area of expertise as it
21 relates to polymer properties and whether or not --
22 if they go out and look at a clinical study, I can
23 look at the polymer testing. Because once you take
24 the polymer out and you do the polymer testing, all
25 of that comes back to polymer science and

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1 **A.** That's a clinical study, if I'm not
2 mistaken. And I believe that's been addressed by
3 Dr. Guelcher.

4 MR. DAVIS: Let's take a break a
5 minute, please.

6 (Brief recess.)

7 BY MR. DAVIS:

8 **Q.** Dr. Dunn, I don't know how else to do
9 this, but there are a number of general questions
10 that you've been asked in prior depositions that
11 I've read, but I guess I'm going to start running
12 through some of them.

13 And I'm assuming the answer is going to
14 be the same, but I don't know that. Things could
15 have changed since your last deposition.

16 **A.** Okay.

17 **Q.** So I'm going to ask you some of them
18 and let's just get a feel for it, and then maybe
19 we'll find a way to cut some of them short --

20 **A.** Okay.

21 **Q.** -- but maybe not.

22 **A.** Okay.

23 **Q.** For instance, have you ever worked with
24 medical implant devices?

25 **A.** Over this litigation over the past two

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1 years -- I have worked for polymer companies, and
2 whether or not those polymers have ended up in
3 medical devices, I don't know.

4 Q. Okay. Have ever had any experience in
5 the design or manufacture of many -- of any medical
6 devices?

7 A. Only insofar as developing polymers
8 that could end up in medical devices, that -- that
9 I can think of at this time.

10 Q. Okay. But -- so you've never actually
11 designed or -- or assisted in the design and
12 manufacture of the device -- a medical device
13 itself, have you?

14 A. No. Other polymer-based devices.

15 Q. Let me -- so you have had experience in
16 the design and development of some polymer-based
17 devices of some sort, right?

18 A. Many. And also the failure analysis of
19 hundreds of polymer-based devices.

20 Q. But were any of those devices medical
21 devices?

22 A. Not that I recall at this time.

23 Q. Okay. Have you ever been hired as a
24 consultant by a medical device company?

25 A. No.

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1 **Q.** Have you ever been hired by a
2 manufacturer related to polypropylene generally?

3 **A.** Not that I recall, but I'm not sure
4 about that. I don't recall.

5 **Q.** Have you ever taught a course, in whole
6 or in part, that dealt with the use of
7 polypropylene in medical devices or its behavior in
8 the body?

9 **A.** I would certainly say in part.

10 **Q.** I'm sorry?

11 **A.** In part, yes.

12 **Q.** What course have you taught that dealt
13 with the use of polypropylene in medical devices?

14 **A.** Courses that I teach on product and
15 process design.

16 **Q.** Okay. Do they deal specifically with
17 medical devices, or is that just general design of
18 products?

19 **A.** I have presented just the same type of
20 information that we presented at the conferences in
21 classes as case studies on failure of devices.

22 **Q.** Okay. But you've never taught a course
23 that involved the use of any of the -- the
24 standards for medical devices that we've talked
25 about today, have you?

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1 **A.** Insofar as I teach FMEAs and require
2 students to do FMEAs and I would tell them, just
3 like I told you before, ISO 14971, in addition to
4 SAE standards -- there's a bunch of standards that
5 have FMEAs. There's not one particular one I make
6 them use.

7 **Q.** But --

8 **A.** I could have them use 14971 as easily
9 as I could have them use the SAE standard.

10 **Q.** Has ISO 14971 been one of your course
11 materials in a course you've taught?

12 **A.** Insofar as I teach FMEAs and FMEAs are
13 covered by ISO 14971. That's my answer.

14 **Q.** I mean, you understand ISO 14971 is
15 a -- is an ISO -- it's available for sale -- for
16 sell -- it's available, right?

17 **A.** Yes, it is.

18 **Q.** So, I mean, your students are required
19 to go buy that ISO or --

20 **A.** No.

21 **Q.** How do they -- how do they use it?

22 **A.** You're saying if I --

23 **Q.** How do they obtain it?

24 **A.** They do not obtain that ISO standard.

25 **Q.** Okay.

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1 **A.** I teach material that is consistent
2 with that ISO standard. That's the best I'm going
3 to answer the question.

4 **Q.** Okay. So they don't actually use that
5 document itself, the ISO 14971, correct?

6 **A.** Not specifically.

7 **Q.** Okay. Have you ever taught a course on
8 medical devices?

9 **A.** Not specifically.

10 **Q.** Have you ever conducted a study as to
11 how polypropylene behaves in the human body?

12 **A.** I've -- I have evaluated explant mesh.
13 I think that has some bearing.

14 **Q.** Okay.

15 MR. BOWMAN: I'm sorry. Could you
16 repeat that last question? I didn't get that at
17 all.

18 MR. DAVIS: I asked has he ever
19 conducted a study as to how polypropylene behaves
20 in the human body.

21 THE WITNESS: I don't know if I'd say
22 it's how -- what were -- what were its properties
23 after it was removed from the human body I've
24 studied.

25

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1 human body?

2 A. The Atlanta presentation that I gave to
3 you was a joint presentation by myself and a
4 colleague.

5 Q. Okay. And what -- what did you have to
6 say in that presentation about the behavior of
7 polypropylene in the human body?

8 A. I don't recall.

9 Q. Okay. Can you tell me just generally
10 what you know about the behavior of polypropylene
11 in the human body?

12 A. I know that, if you have reactive
13 oxygen species present, that it will oxidize. If
14 it oxidizes, it breaks the long chain links of the
15 polymers into shorter chain links. You form
16 cracks. It gets brittle and hard.

17 Q. And you had -- you were careful to give
18 me two ifs in that answer; is that correct?

19 A. I think there was one, "if you have
20 reactive oxygen species present."

21 Q. Okay. Well, it will speak for itself.

22 A. Okay. Was there more than one "if"?

23 Q. I'm not going to argue about it.

24 A. Okay.

25 Q. Have you ever published an article

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1 concerning the use of polypropylene in medical
2 devices?

3 A. No.

4 Q. Have you ever published an article
5 concerning medical devices in general, or any of
6 them?

7 A. Not specifically, no.

8 Q. Okay. Have you ever published an
9 article or given a presentation regarding quality
10 control systems relating to a medical device
11 manufacturing facility?

12 A. Not relating to a medical device
13 manufacturer.

14 Q. Have you ever published an article or
15 given a presentation regarding the postmarket
16 surveillance of medical devices?

17 A. No.

18 Q. Am I correct that your doctoral thesis
19 dealt with waste minimization or large-scale
20 process design?

21 A. Yes. That would probably be as good a
22 characterization as you can do.

23 Q. Okay.

24 A. Well, it also involved some polymer
25 effects, too, if I recall.

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1 **Q.** Did your doctoral thesis deal in any
2 way with medical devices?

3 **A.** No.

4 **Q.** Did it deal with polypropylene's --
5 with polypropylene's behavior in the human body?

6 **A.** No.

7 **Q.** This is similar to a question I asked
8 earlier: Have you had any work experience with the
9 design or manufacture of a medical device?

10 **A.** I have extensive experience in both
11 polymer manufacturing and polymer failure analysis,
12 which is easily extended to medical devices.

13 **Q.** But have you had any experience in the
14 design and manufacture of the device itself, the
15 medical device itself?

16 **A.** I consider the manufacture of polymers
17 and the failure analysis of polymer products
18 related --

19 **Q.** Okay.

20 **A.** -- for what a chemical engineer does.

21 **Q.** Have you ever written any books or
22 chapters in books regarding medical device
23 manufacturing?

24 **A.** No.

25 **Q.** Do you have any work experience with

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1 polypropylene behavior in vivo?

2 A. Only what I've done on mesh-related
3 cases.

4 Q. Okay. And only that which you've
5 already explained, or is there something new you
6 need to tell me about?

7 A. With respect to Ethicon, yes. We've
8 only talked about Ethicon.

9 Q. Okay. Well, what other work experience
10 do you have with polypropylene behavior in vivo?

11 A. Other than what we've discussed today?
12 Other mesh-related cases.

13 Q. Would you estimate you've been retained
14 in more than 100 legal cases?

15 A. Yes, I would.

16 Q. And would you agree that the pelvic
17 mesh litigation is your first time for being
18 retained in a case involving medical devices?

19 A. Medical devices, but certainly not
20 polypropylene.

21 Q. Okay. It is the first time you've been
22 retained for cases dealing specifically with
23 medical devices, correct?

24 A. I thought I answered it clearly,
25 that --

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1 **Q.** I want to limit it not to
2 polypropylene, but just to medical devices
3 specifically.

4 **A.** I'm -- I'll answer it that I have been
5 retained -- I've never been retained to look at
6 other medical devices that I can recall, but that
7 does not include evaluating polypropylene.

8 **Q.** Fair enough. Have you ever published
9 in a medical journal?

10 **A.** No.

11 **Q.** Have you ever been involved in
12 developing a failure modes and effects analysis for
13 a medical device?

14 **A.** I don't know.

15 (Reporter interruption for
16 clarification.)

17 THE WITNESS: I said I don't know.

18 BY MR. DAVIS:

19 **Q.** Do you agree that you are not qualified
20 to offer opinions on how polypropylene reacts
21 inside the body?

22 **A.** I think I've clearly answered this
23 numerous times today, that I know what happens when
24 polypropylene oxidizes as a polymer expert, and I
25 know what that oxidation does to the properties.

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1 **Q.** Okay. Well, you haven't evaluated the
2 clinical safety of Prolene meshes, have you?

3 **A.** I have not.

4 **Q.** Okay. Would you agree, you're not
5 qualified to discuss the clinical effects of
6 Prolene mesh in the body?

7 **A.** I have not -- that's not part of what
8 I've covered in my report.

9 **Q.** Okay. Do you have any expertise in
10 determining whether there's any clinical risk from
11 degradation of Prolene mesh in the body?

12 **A.** I have not covered that in my report.

13 **Q.** Are you aware of any literature
14 suggesting that there is any clinical risk from
15 degradation of Prolene mesh in the body?

16 MR. BOWMAN: This was asked and
17 answered, but. . .

18 THE WITNESS: I am aware of literature
19 that talks about the degradation of polypropylene
20 in the body.

21 BY MR. DAVIS:

22 **Q.** But that's not my question. I'm
23 talking about clinical risk.

24 Are you aware of any literature that's
25 suggesting that there's any clinical risk?

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1 **A.** I haven't evaluated that as part of my
2 report.

3 **Q.** Okay. By the way, your presentations
4 that we've talked about, the two presentations,
5 were they funded by some -- by a third party?

6 **A.** They were funded by Polymer and
7 Chemical Technologies.

8 **Q.** Okay. Who is Polymer and Chemical
9 Technologies?

10 **A.** That's my company.

11 **Q.** Okay.

12 **A.** They funded all of those studies.

13 **Q.** Okay. Plaintiff's counsel were not --
14 did not participate in that funding?

15 **A.** They did not fund the suture or the in
16 vitro study.

17 **Q.** Okay. In the past, you were -- you
18 were asked about some work you were planning to do
19 in the future, and you were asked the question,
20 "And is it being funded by counsel?"

21 And you answered, "It is."

22 Have you done any studies or planned
23 any studies that were being funded by counsel?

24 **A.** At one time we talked about looking at
25 some studies that would be funded by counsel. But,

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1 **A.** Certain parts of chemistry, certainly,
2 like analytical chemistry, polymer chemistry,
3 pretty good.

4 **Q.** Okay. Okay.

5 Are you a materials scientist expert?

6 **A.** Only as it relates to polymers.

7 **Q.** And are you an expert in
8 biocompatibility?

9 **A.** No.

10 **Q.** Are you an expert in the female
11 anatomy?

12 **A.** No. I would have to say no.

13 **Q.** And I -- I'm just trying to be
14 complete.

15 **A.** I understand.

16 **Q.** And you're not a regulatory expert of
17 any kind, are you?

18 **A.** No.

19 **Q.** Okay. Have you got any expertise in
20 the proper methods for cleaning explanted mesh
21 before studying it?

22 **A.** No.

23 **Q.** Okay. And I think you've already said
24 you have no -- no knowledge really of Ms. Jasso at
25 all?

C E R T I F I C A T E

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

I, Lise S. Matthews, RMR, CRR, CCP, LCR 353, Licensed Court Reporter and Notary Public, in and for the State of Tennessee, do hereby certify that the above deposition was reported by me, and the transcript is a true and accurate record to the best of my knowledge, skills, and ability.

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